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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------|-----------------|----------------------|---------------------|------------------|
| 10/750,143 | 12/31/2003 | Maurice Behague | 069208.0115 7930 | |
| 23640 BAKER BOTT | 7590 05/07/200° | | EXAMINER | |
| 910 LOUISIAN | NA . | | HAND, MELANIE JO | |
| HOUSTON, TX 77002-4995 | | | ART UNIT | PAPER NUMBER |
| | | | 3761 | |
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| | | | MAIL DATE | DELIVERY MODE |
| | | | 05/07/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



| | Application No. | Applicant(s) | | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|-----------------------|--|--|--|
| | 10/750,143 | BEHAGUE ET AL. | | | |
| Office Action Summary | Examiner | Art Unit | | | |
| | Melanie J. Hand | 3761 | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | |
| Status | , | | | | |
| Responsive to communication(s) filed on 14 Fe This action is FINAL. Since this application is in condition for alloware closed in accordance with the practice under E | action is non-final. | • | | | |
| Disposition of Claims | parto quajio, 1000 G.D. 11, 10 | | | | |
| 4) Claim(s) 1-17 is/are pending in the application. 4a) Of the above claim(s) 6-17 is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1-5 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. | | | | | |
| Application Papers | | | | | |
| 9) ☐ The specification is objected to by the Examiner. 10) ☑ The drawing(s) filed on 12/31/03 is/are: a) ☑ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 3/30/04. | 4) Interview Summary Paper No(s)/Mail Di 5) Notice of Informal F 6) Other: | ate | | | |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I, claims 1-5 in the reply filed on February 14, 2007 is acknowledged. The traversal is on the ground(s) that there should not be a restriction between groups II and III because the combination does require the particulars of the subcombination. This is not found persuasive because, while the combination does require the particulars of the subcombination as noted by applicant, the restriction between claims 6-27 and the method claims 1-5 is still valid.

The requirement is still deemed proper and is therefore made FINAL.

Claims 6-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on February 14, 2007.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on March 30, 2004 was filed after the mailing date of the application on December 31, 2003. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

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Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be <u>material to patentability</u> as defined in 37 CFR 1.56.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Riordan et al (EP 583,148 A2).

With respect to **claim 1:** O'Riordan teaches a method of collecting a biological fluid comprising: collecting a biological fluid by natural flow via a needle (Page 3, lines 45-47); measuring a fluid flow rate of the biological fluid via flow detector 22 (Page 5, lines 19-21); and pumping anticoagulant and/or preservation solution to the collected biological fluid at a solution flow rate (page 3, lines 54,55); wherein the solution flow rate is adjusted while collecting the biological fluid based upon the measured fluid flow rate to preserve a selected ratio between the collected biological fluid and the anticoagulant and/or preservation solution. (Page 3, lines 54,55; Page 4, lines 15-33)

With respect to **claim 2**: The method taught by O'Riordan further comprises: collecting the biological fluid in a collection bag 16 (Fig. 4, Page 4, lines 53-55); and pumping the anticoagulant and/or preservation solution to the collection bag 16 (Page 4, lines 53-55); wherein the solution flow rate is adjusted while collecting the biological fluid based upon the measured fluid flow rate Qb to preserve a selected ratio in the collection bag 16 between the collected biological fluid and the anticoagulant and/or preservation solution. (Page 4, lines 15-33)

With respect to claim 3: The biological fluid comprises blood. (Abstract)

With respect to **claim 5**: The method taught by O'Riordan comprises a step of pumping anticoagulant, wherein pumping comprises: pumping using a peristaltic pump 42 having a variable rotation speed in that the minimum pump speed can be set and the operation of the pump is controlled to ensure maintenance of the desired flow rate of anticoagulant (Page 3, lines 54,55; Page 5, lines 4,5); and adjusting the variable rotation speed to obtain the appropriate solution flow rate. (Page 3, lines 54,55; Page 5, lines 4,5)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'Riordan et al ('148).

With respect to claim 4: The method taught by O'Riordan comprises a step of measuring a fluid flow rate Qb, wherein measuring a fluid flow rate of the biological fluid comprises calculating the variation in volume of the fluid collected, wherein such volume has an associated weight directly correlated to said volume by the density of the biological fluid. O'Riordan does not teach that measuring a fluid flow rate of the biological fluid comprises calculating the variation in weight of the fluid collected. However, the data accumulated by performing the step of measuring the variation in volume can be used to calculate variation in weight by multiplying the variations in volume by the density of the fluid (know because the fluid is blood) and multiplying the resulting mass variation by the gravitational constant to produce the associated weight variations.

Therefore it would be obvious to one of ordinary skill in the art to modify the method taught by O'Riordan such that the step of measuring fluid flow rate Qb further comprises the step of calculating the variation in weight of fluid collected with a reasonable expectation of success.

Double Patenting

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-21 of copending Application No. 11/196,706. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are a broader recitation of the claims of the copending application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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May 2, 2007

TATYANA ZALUKAEVA SUPERVISOBX PRIMARY EXAMINER